

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

BIOGEN IDEC MA INC.,)
vs.)
Plaintiff,)
JAPANESE FOUNDATION FOR)
CANCER RESEARCH;)
KYOWA HAKKO KIRIN CO., LTD.;)
TORAY INDUSTRIES, INC.; and BAYER)
PHARMA AG)
Defendants.)

)

Civil Action No. _____

COMPLAINT

Plaintiff, Biogen Idec MA Inc. (“Biogen Idec”), alleges as follows for its complaint against Defendants, Japanese Foundation for Cancer Research (“JFCR”), Kyowa Hakko Kirin Co., Ltd. (“Kyowa”), Toray Industries, Inc. (“Toray”), and Bayer Pharma AG (“Bayer”) (collectively, “Defendants”):

NATURE OF THE ACTION

1. This is an action under 35 U.S.C. §146 to review and correct the rulings of the Patent Trial and Appeal Board (the “Board”) of the United States Patent and Trademark Office (the “PTO”) in Interference No. 105,939 (the “939 Interference”) between a patent application filed in the name of Walter C. Fiers (“Fiers”) and a patent application filed in the names of Haruo Sugano, Masami Muramatsu and Tadatsugu Taniguchi (“Sugano”), including the Decision, Fiers Response to Order to Show Cause (Paper No. 78) (the “Decision”) (copy attached as Exhibit A)

and the Judgment Bd. R. 127 (a)(1) (Paper No. 79) (the “Judgment”) (copy attached as Exhibit B) and to decide all issues that were before the PTO in the ‘939 Interference.

PARTIES

2. Biogen Idec is a Massachusetts corporation with an office and principal place of business at 14 Cambridge Center, Cambridge, MA 02142. Biogen Idec is the assignee of the Fiers patent application involved in the ‘939 Interference.

3. Upon information and belief, JFCR is a non-profit entity organized and existing under the laws of Japan, with an office and principal place of business at 3-8-31, Ariake, Koto-ku, Tokyo 135-8550 Japan. Upon information and belief, JFCR is the assignee of the Sugano patent application involved in the ’939 Interference.

4. Upon information and belief, Kyowa is a corporation organized and existing under the laws of Japan having a principal place of business at 1-6-1, Otemachi, Chiyoda-ku, Tokyo 100-8185, Japan.

5. Upon information and belief, Toray is a corporation organized and existing under the laws of Japan, having a principal place of business at 2-1-1, Nihonbashi-Muromachi, Chuo-ku, Tokyo 103-8666, Japan.

6. Upon information and belief, Bayer is a corporation organized and existing under the laws of Germany with a principal place of business at Müllerstrasse 178, 13353 Berlin, Germany.

7. During the ’939 Interference proceedings, party Sugano identified each of the Defendants as a real party in interest. (Paper No. 5). In naming the Defendants in this Action, Biogen Idec relies on party Sugano’s statement to the PTO, and the text of 35 U.S.C. §146,

which states in part that “suit may be instituted against the party in interest as shown by the records of the Patent and Trademark Office at the time of the decision complained of.”

JURISDICTION AND VENUE

8. This court has subject matter jurisdiction pursuant to 35 U.S.C. §146 and 28 U.S.C. §§ 1331 and 1338(a).

9. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b)-(c).

10. This Court has jurisdiction over Defendants based, on information and belief, on their substantial contacts with this judicial district. Upon information and belief, jurisdiction is conferred, at least in part, upon Defendants based on the activities of JFCR employee Tadatsugu Taniguchi in this judicial district that led to the Sugano et al. patent application involved in this case. Upon information and belief, jurisdiction is also conferred, at least in part, because certain rights of Defendants JFCR, Kyowa and Toray in the Sugano patent application involved in the '939 Interference have been transferred to Plaintiff Biogen Idec in this judicial district. Upon information and belief, jurisdiction over Defendants is also conferred, at least in part, based on their continuous and systematic contacts with this judicial district either directly or through U.S. subsidiaries and affiliates, over which, upon information and belief, those Defendants exercise control.

STATEMENT OF THE FACTS

11. Human fibroblast interferon (“hFIF”) is a human protein that possesses valuable antiviral and immunological activities. Plaintiff, Biogen Idec, discovered, developed, obtained U.S. Food and Drug Administration approval of and commercially sells a form of recombinant hFIF under the trademark Avonex®. Avonex® is a biopharmaceutical product which is an important therapy for the treatment of multiple sclerosis.

12. Biogen Idec is the owner of United States patent application 08/253,843 that was filed on June 3, 1994 in the name of Walter C. Fiers (the “Fiers ’843 Application”). The Fiers ’843 Application is entitled “DNA Sequences, Recombinant DNA Molecules and Processes for Producing Human Fibroblast Interferon-like Polypeptides.” The Fiers ’843 Application was filed pursuant to 35 U.S.C. §121 as a division of Fiers’ earlier application no. 07/387,503, filed July 28, 1989 (the “Fiers ’503 Application”), which was a division of application no. 06/250,609, filed on April 3, 1981 (the “Fiers ’609 Application”). The Fiers ’843 Application claims priority to the Fiers ’609 Application pursuant to 35 U.S.C. § 120. The Fiers ’843 Application also claims priority under 35 U.S.C. § 119 to British patent applications 80.18701, filed June 6, 1980, and 80.11306, filed April 3, 1980.

13. Upon information and belief, JFCR is the owner of U.S. patent application 08/463,757, filed June 5, 1995 in the names of Haruo Sugano, Masami Muramatsu and Tadatsugu Taniguchi (the “Sugano ’757 Application”). The Sugano ’757 Application claims priority under 35 U.S.C. § 120 to U.S. application number 08/400,179, filed March 6, 1995, application number 06/389,922, filed June 18, 1982, and U.S. application 06/201,359, filed October 27, 1980 (the “Sugano ’359 Application”). The Sugano ’757 Application also claims priority under 35 U.S.C. § 119 to Japanese patent application number 33931/80, filed March 19, 1980.

14. Both the Fiers ’843 Application and the Sugano ’757 Application contain claims to human fibroblast interferon proteins. The PTO declared the ’939 Interference between those patent applications on July 16, 2013. In declaring the interference, the PTO defined the interfering subject matter with two counts. Count one read:

Recombinant human fibroblast β_1 interferon having the amino acid sequence:

Met Ser Tyr Asn Leu Leu Gly Phe Leu Gln Arg Ser Ser Asn Phe Gln Cys Gln Lys Leu Leu Trp Gln Leu Asn Gly Arg Leu Glu Tyr Cys Leu Lys Asp Arg Met Asn Phe Asp Ile Pro Glu Glu Ile Lys Gln Leu Gln Gln Phe Gln Lys Glu Asp Ala Ala Leu Thr Ile Tyr Glu Met Leu Gln Asn Ile Phe Ala Ile Phe Arg Gln Asp Ser Ser Ser Thr Gly Trp Asn Glu Thr Ile Val Glu Asn Leu Leu Ala Asn Val Tyr His Gln Ile Asn His Leu Lys Thr Val Leu Glu Glu Lys Leu Glu Lys Asp Phe Thr Arg Gly Lys Leu Met Ser Ser Leu His Leu Lys Arg Tyr Gly Arg Ile Leu His Tyr Leu Lys Ala Lys Glu Tyr Ser His Cys Ala Trp Thr Ile Val Arg Val Glu Ile Leu Arg Asn Phe Tyr Phe Ile Asn Arg Leu Thr Gly Tyr Leu Arg Asn.

Count 2 read:

Recombinant human fibroblast β_1 interferon having the amino acid sequence:

Met Thr Asn Lys Cys Leu Leu Gln Ile Ala Leu Leu Cys Phe Ser Thr Thr Ala Leu Ser Met Ser Tyr Asn Leu Leu Gly Phe Leu Gln Arg Ser Ser Asn Phe Gln Cys Gln Lys Leu Leu Trp Gln Leu Asn Gly Arg Leu Glu Tyr Cys Leu Lys Asp Arg Met Asn Phe Asp Ile Pro Glu Glu Ile Lys Gln Leu Gln Gln Phe Gln Lys Glu Asp Ala Ala Leu Thr Ile Tyr Glu Met Leu Gln Asn Ile Phe Ala Ile Phe Arg Gln Asp Ser Ser Ser Thr Gly Trp Asn Glu Thr Ile Val Glu Asn Leu Leu Ala Asn Val Tyr His Gln Ile Asn His Leu Lys Thr Val Leu Glu Glu Lys Leu Glu Lys Asp Phe Thr Arg Gly Lys Leu Met Ser Ser Leu His Leu Lys Arg Tyr Gly Arg Ile Leu His Tyr Leu Lys Ala Lys Glu Tyr Ser His Cys Ala Trp Thr Ile Val Arg Val Glu Ile Leu Arg Asn Phe Tyr Phe Ile Asn Arg Leu Thr Gly Tyr Leu Arg Asn.

Claims 16, 32, 33, and 38-40 of the Fiers '843 Application and claims 4, 30, 31, 36, 39-44, 46, 48, and 49 of the Sugano '757 Application were designated as corresponding to Count 1. Claims 16, 31-33, 35 and 38 of the Fiers '843 Application and claims 4, 30 and 32 of the Sugano '757 Application were designated as corresponding to Count 2.

15. Count 1 of the '939 Interference is directed to "mature" forms of hFIF. Count 2 of the interference is directed to the precursor forms of hFIF. The active form of the protein is a mature form of the protein. Mature hFIF lacks a 21-amino acid signal sequence that is present in the precursor forms of the protein. When hFIF is produced naturally, the body's cells secrete the

active mature form of the protein. Biogen Idec's Avonex® product contains a mature form of hFIF protein.

16. At the time that the PTO declared the '939 Interference, it also issued an Order to Show Cause - Bd.R202(d)(2). (Paper No. 3). The PTO ordered Fiers to show why judgment should not be entered against him under principles of interference estoppel and issue preclusion, based on the outcome of an earlier interference no. 101,096 (the "'096 Interference") between Fiers' and Sugano's parent applications.

17. The '096 Interference was declared by the PTO on August 30, 1983 between the Fiers '609 Application and the Sugano '359 Application. That interference was directed to hFIF DNA and was defined by a single count which read: "A DNA which consists essentially of a DNA which codes for a human fibroblast interferon-beta polypeptide." The '096 Interference count did not distinguish between DNA encoding the precursor protein and DNA encoding the mature protein. The PTO Board of Patent Appeals and Interferences awarded priority to Sugano with respect to the hFIF DNA subject matter and the U.S. Court of Appeals for the Federal Circuit affirmed. *Fiers v. Revel*, 984 F.2d 1164 (Fed. Cir. 1993).

18. The count in the '096 Interference and the parties' claims corresponding to that count were all directed to DNA encoding hFIF. In contrast, all of the claims and counts of the '939 Interference – the interference of which Biogen Idec seeks review in this Complaint – are directed to hFIF proteins.

19. The Fiers '609 Application that was involved in the '096 Interference originally contained claims, *inter alia*, to both hFIF DNA and hFIF proteins. During prosecution of that application, the PTO issued a Restriction Requirement requiring Fiers to select either DNA claims or protein claims for continued prosecution. In issuing the Restriction Requirement, the

patent examiner stated that restriction was required, because the DNA claims and the protein claims are “distinct” and “can support separate patents.” In response to the Restriction Requirement, Fiers elected to pursue claims directed to DNA sequences. Fiers withdrew the claims directed to the hFIF protein from the Fiers ’609 Application.

20. As permitted under 35 U.S.C. §121, the Fiers ’843 Application that is involved in the present ’939 Interference was filed in 1994 to pursue the recombinant protein claims that the PTO required to be restricted out of the original Fiers ’609 Application during its prosecution.

21. In 2007, during prosecution of the Fiers ’843 Application, the examiner rejected the claims as anticipated by U.S. Patent Nos. 5,326,859 (“the Sugano ’859 patent”) and 5,514,567 (“the Sugano ’567 patent”). Fiers appealed the examiner’s rejection, and the Board of Patent Appeals and Interferences reversed. In reversing, the Board concluded that “the Examiner has not established an evidentiary basis on this record to support a conclusion that [Fiers’] claimed recombinant polypeptide [*i.e.*, hFIF protein], composition, and method are patentably indistinguishable over...the DNA claims [encoding hFIF protein].” Following the Board’s reversal, the examiner issued an action stating that all claims were allowable, but suspended *ex parte* prosecution due to a potential interference. Prosecution of the ’843 application was subsequently suspended several more times, and the ’939 Interference was declared following conclusion of interferences between Sugano and another party, Goeddel et al.

22. Fiers responded to the PTO’s July 26, 2013 Order to Show Cause in the ’939 Interference (“the Fiers Response”) on August 12, 2013. (Paper No. 49). Sugano filed an Opposition to the Fiers Response to the Order to Show Cause (“the Sugano Opposition”) on September 6, 2013. (Paper No. 64). Fiers filed a Reply to Sugano’s Opposition to the Fiers

Response to Order to Show Cause (“the Fiers Reply”) on September 25, 2013. (Paper No. 69). Fiers’ request for an oral hearing was denied.

23. On October 3, 2013, the Board issued its Decision and entered its Judgment in the ’939 Interference. The Board erroneously found that as a result of the outcome of the earlier ’096 Interference, Fiers was estopped from claiming the subject matter of both counts –the mature and precursor recombinant hFIF proteins.

24. As a result of the Board’s Decision, the Board entered judgment against Fiers in the ’939 Interference, and ordered that all of the claims in the Fiers ’843 Application be finally refused.

25. Prior to the Board’s entry of Judgment and pursuant to the applicable PTO rules and the Board’s Standing Order (Paper No. 2), Fiers filed a paper (Paper No. 65) raising the issues of its intended motions described below. As a consequence of its Decision and entry of Judgment, the Board precluded decision on these issues and motions and thereby effectively denied them.

A. Contingent on a finding that claims to hFIF DNA and hFIF proteins are not patentably distinct, a motion pursuant to 37 C.F.R. §§41.121(a)(1)(iii) and 41.208(a)(1) that, based on admissions by Senior Party Haruo Sugano, Masami Muramatsu and Tadatsugo Taniguchi (“Sugano”) in its Opposition to Fiers’ Response to the Order to Show Cause (“Sugano’s Opposition”), judgment should be entered against Sugano as to both Count 1 and Count 2 for obviousness-type double patenting over expired U.S. Patent No. 5,326,859, issued July 5, 1994 (“the ’859 patent”).

B. A motion pursuant to 37 C.F.R. §§41.121(a)(1)(iii) and 41.208(a)(1) that Sugano does not have 35 U.S.C. §112, first paragraph written description and enablement support for Count 1 or Count 2, because the Sugano ’757 Application only describes the

means for producing the DNA encoding the precursor hFIF protein in *E. coli* (i.e., only cloning vectors, not expression vectors). The Sugano '757 Application does not describe any means for expressing proteins, much less for expressing them in mammalian cells which is required for correct glycosylation to occur. It provides no starting materials, vectors, control sequences, methods for detecting expression or any of the other details that would be required for producing the proteins, and does not point to any prior art procedures or cite to any references that would be enabling for the expression of hFIF proteins.

C. Motion pursuant to 37 C.F.R. §§41.121(a)(1)(ii) and 41.208(a)(3) and Standing Order §208.4.2 that Sugano is not entitled to the benefit of any of U.S. Application Serial Nos. 08/400,179, filed March 6, 1995, 06/389,922, filed June 18, 1992 or 06/201,359, filed October 27, 1980, or Japanese Application No. 33931/80, filed March 19, 1980 for either Count 1 or Count 2, for the reasons discussed with respect to the motion described in Paragraph B, above and the fact that the U.S. Court of Appeals for the Federal Circuit has held that the Sugano March 19, 1980 Japanese application does not describe the DNA encoding the mature hFIF of Count 1, much less the mature hFIF protein.

D. Motion pursuant to 37 C.F.R. §41.121(a)(1)(iii) and 41.208(a)(1) for judgment that Sugano Claims 4, 30, 31, 32, 36, 39-44, 46 and 48-49 are unpatentable under 35 U.S.C. §102(e) as anticipated by, or under 35 U.S.C. §102(e)/35 USC §103 as obvious, in view of U.S. Patent No. 7,588,755, issued September 15, 2009 or 7,635,466, issued December 22, 2009, both claiming benefit to U.S. Application Serial No. 06/250,609, filed April 3, 1981.

E. Motion pursuant to 37 C.F.R. §§41.121(a)(1)(iii) and 41.208(a)(4) and Standing Order §208.6 that Fiers is entitled to priority.

COUNT I

26. Biogen Idec hereby incorporates paragraphs 1 - 25 above as if set forth in full herein.

27. Pursuant to 35 U.S.C. §146, Biogen Idec has elected to file suit in this Court to review and reverse the Board's Decision and Judgment and to decide all issues raised before the Board. Biogen Idec has not sought review of the Board's Decision by the United States Court of Appeals for the Federal Circuit.

28. The Board's Decision and Judgment in the '939 Interference are erroneous and, based on the record before the Board and any additional evidence Biogen Idec may introduce in this action, Biogen Idec is entitled to judgment correcting the erroneous Decision and Judgment of the Board.

29. The Board erred in ruling that the subject matter of Counts 1 and 2 of the '939 Interference and claims corresponding thereto were not patentably distinct from the subject matter of the Count and involved claims of the '096 Interference.

30. In view of the fact that the PTO had previously issued a Restriction Requirement in the Fiers '609 Application holding hFIF DNA and hFIF protein claims to be "distinct" and capable of supporting separate patents, and in further view of the fact that the hFIF protein claims were prosecuted in the Fiers '843 Application as a result of the PTO's Restriction Requirement, the Board erred in its ruling that hFIF DNA claims and hFIF protein claims are not patentably distinct from each other.

31. The Board erred in ruling that hFIF DNA claims and hFIF protein claims are not patentably distinct in view of the PTO's repeated and consistent holdings that such claims are

patentably distinct.

32. The Board erred in ruling that claims to functional human fibroblast interferon would have been obvious over disclosure of the nucleotide sequence of hFIF precursor DNA disclosed in Sugano's Japanese priority application no. 33931/80.

33. The Board erred in ruling that party Fiers was precluded by principles of interference estoppel and issue preclusion from obtaining claims corresponding to Count 1 and Count 2 of the '939 Interference.

34. The Board erred in ruling that party Fiers could have raised the issues of priority between Counts to hFIF proteins and claims corresponding thereto in the '096 Interference under the PTO rules and applicable law then in effect.

35. The Board erred in concluding that Fiers had not properly attempted to introduce a count directed to hFIF proteins in the '096 Interference.

36. The Board erred in effectively denying the Fiers motions identified in Paragraph 25 above.

37. The Board erred in summarily deciding contested issues of fact on an Order to Show Cause.

PRAYER FOR RELIEF

WHEREFORE, based on the foregoing allegations and claims, Plaintiff, Biogen Idec, requests that the Court enter judgment in its favor and award it the following relief:

- A. Reversing the Board's Decision and Judgment;
- B. Awarding priority to Fiers with respect to the subject matter of Counts 1 and 2 of the '939 Interference;
- C. Finding that all Fiers claims corresponding to Counts 1 and 2 of the '939 Interference

are patentable to Fiers and all Sugano claims corresponding to Counts 1 and 2 of the '939

Interference are not patentable to Sugano;

D. Reversing the Board's Decision and Judgment that Fiers is estopped from claiming

the subject matter of the '939 Interference counts on the basis of interference estoppel;

E. Awarding Biogen Idec its costs and fees incurred in this action; and

F. Granting any such other relief as the Court deems just and appropriate.

Dated: December 2, 2013

Respectfully submitted,

Of Counsel:

E. Anthony Figg

R. Danny Huntington

Sharon E. Crane

Seth E. Cockrum

ROTHWELL, FIGG, ERNST &

MANBECK, P.C.

607 14th Street, NW

Suite 800

Washington, DC 20005

Phone: (202) 783-6040

Fax: (202) 783-6031

/s/ Claire Laporte

Donald R. Ware (BBO# 516260)

Claire Laporte (BBO# 554979)

FOLEY HOAG LLP

Seaport World Trade Center West

155 Seaport Boulevard

Boston, MA 02210-2600

Phone: (617) 832-1000

Fax: (617) 832-7000

dware@foleyhoag.com

claporte@foleyhoag.com

Counsel for Plaintiff